

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of  
Giuseppe Maio

Serial No. 10/792,100                      Group Art Unit: 1616  
Filed: March 3, 2004      Examiner: Landau, Sharmila Gollamudi

For: COSMETIC COMPOSITION CONTAINING POLYISOPRENE

DECLARATION UNDER 37 CFR § 1.132

Honorable Commissioner  
of Patent and Trademarks  
Washington, D.C. 20231

Sir:

I, Giuseppe Maio, a citizen of Italy, hereby declare and state:

1. I attended a Technical School (I.T.I.S.) in Salerno (Italy) with specialisation in Chemistry, where I obtained a diploma in 1965. From 1966 to 1967 I had a job in the food analysis department of Cirio S.p.A. in Naples and from 1967 to 1986 I worked in the cosmetic field in some cosmetic companies in Milan, particularly as R&D Manager for Cosmetic Make-up in International Chemical Cosmetic & Company S.p.A. in Milan from 1980 to 1986. Since 1986 to date I have been Exploratory Research Manager in the Assignee company Interco S.p.A. I am inventor and applicant in several US patents such as US 6,372,232, US 6,660,253, US 6,953,543.

2. I am the inventor of the above referenced patent application and I am familiar with the references applied in the Office Action mailed December 16, 2008.

3. Cosmetic products for make-up of face, lips, eyelashes etc often suffer from the drawback that, when they come into contact with e.g. the fingers or clothing, they tend to smudge or solid these surface. In addition, in some cases the make-up can also appear to be not homogeneous.

Therefore, in order to avoid these problems cosmetic products suitable for application to facial skin, lips and eyelashes have to be endowed with the following properties: be stable, have high film-forming property and provide for the deposition of a homogeneous, long lasting film onto the facial skin, the lips and the eyelashes.

4. I made a lot of experiments in order to select the specific components for a cosmetic composition capable of being endowed with the all the above required properties.

During my experiments, I have surprising found that the combination of 1) a polyisoprene (from 2 to 25% (w/w)) obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range, 2) disteardimonium hectorite (0.05 to 20% (w/w)) and 3) isododecane (from 1.1 to 90% (w/w)), the balance comprising conventional cosmetic excipients, colourants and additives, is critical in order to achieve an anhydrous cosmetic composition which is stable and provides for the deposition of a homogeneous, long lasting film onto the facial skin, the lips and the eyelashes.

In order to obtain the above desired anhydrous composition, I have performed the following assays which results are depicted below.

In my experiments I have compared the properties of the following products:

- "REM 513.32" is an invention product with the following composition: a polyisoprene (10.0% w/w) obtained by the process comprising the steps of a) comminuting the solid polyisoprene Kraton IR 310 with a molecular weight of about 3,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight of about 100,000; disteardimonium hectorite Bentone 38V (6.0% w/w); isododecane (79.0% w/w); and colourants (5.0% (w/w)).

- "REM 513.33" is a comparable product having the same composition of the invention product REM 513.32 but without disteardimonium hectorite.

In particular, REM 513.33 has the following composition: a polyisoprene (10.0% w/w) obtained by the process comprising the steps of a) comminuting the solid polyisoprene Kraton IR 310 with a molecular weight of about 3,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight of about 100,000; isododecane (85.0% w/w); and colourants (5.0% (w/w)).

- "REM 513.34" is a comparable product having the same composition of the invention product REM 513.32 but wherein the invention polyisoprene obtained by the process comprising the steps of a) comminuting the solid polyisoprene Kraton IR 310 with a molecular weight of about 3,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight of about 100,000, is substituted with a polyisoprene latex.

In particular, REM 513.34 has the following composition: polyisoprene latex IR401B (15.0% w/w), disteardimonium

hectorite Bentone 38V(6.0% w/w); isododecane (73.5% w/w); and colourants (5.0% (w/w).

The properties of the above tested composition have been summarized below.

**REM 513.32**

Aspect: Creamy fluid stable product endowed with high long lasting film properties.

Drying time after application: 3 minutes

**REM 513.33**

Aspect: Liquid unstable product, after 2 hours from its preparation the product shows an evident colour phase separation and thus making the product not applicable.

Drying time after forced application: 6 minutes

**REM 513.34**

Aspect: Doughy unstable product, visually unhomogeneous and thus making the product not applicable.

Drying time after forced application: 10 minutes

The film-forming property of the above products (i.e. REM 513.32, REM 513.33 and REM 513.34) has been measured by means of the following transferability resistance test and saliva resistance test.

It is to be noted that, in order to carry out the above tests, the instable comparable products REM 513.33 and REM 513.34 have been previously made homogeneous.

**Transferability Resistance Assay**

The products have been applied on standard Leneta paper (Leneta 3NT-2 Translucent black & white) by means of a bar coated 10 microns applicator with the automatic applicator Elcometer at

speed 11. After 5' drying, the sample was coupled with Leneta 3NT-2 paper, applied onto the automatic applicator and wiped with a 1Kg bar for 10 wipes. The transferability of the products from the applied paper to the coupled paper has been assessed.

After 10 wipes

REM 513.32	REM 513.33	REM 513.34
No transfer	Very poor transfer	Poor transfer

It is to be noted that the films of the comparable product REM 513.34 deposited on the paper were visually unhomogeneous. As far as the comparable product REM 513.34 is concerned, it showed very evident colour streaks and its deposited film was easily removed by means of a finger wipe.

#### Saliva Resistance Assay

The products have been applied on standard Leneta paper (Leneta 3NT-2 Translucent black & white) by means of a bar coated 10 microns applicator with automatic applicator Elcometer at speed 11. After 60' drying, the sample has been applied onto the automatic applicator and wiped with a uniformly wetted tampon of 1 g standard synthetic saliva fluid with a 1 Kg weight for five wipes in order to assess the product dissolution and its transferability onto the tampon.

After 5 wipes

REM 513.32	REM 513.33	REM 513.34
Clean tampon, no colour transfer	Slightly colour dirty tampon, slight ring	Slightly colour dirty tampon, slight ring

5. From the above experimental data, it is evident that the combinative effect of the presence of the three specific components selected, i.e. 1) the polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range, 2) disteardimonium hectorite and 3) isododecane (REM 513.32) is essential in order to achieve a stable anhydrous cosmetic composition endowed with high film-forming property, which is easy to use and stable over a medium-long term and which provides for the deposition of a homogeneous long lasting film on the facial skin, lips and eyelashes.

Indeed, as shown from the above data, only the invention product (REM 513.32) is endowed with a homogeneous creamy fluid aspect, has good film-forming property and a short drying time after application which makes it easy to use.

Furthermore, from the data shown above, it is also evident that the invention products (REM 513.32) is also a stable product.

On the contrary, all the comparative products (REM 513.33 and REM 513.34) are unstable and with an unhomogeneous aspect and therefore unsuitable for the preparation of a cosmetic composition for application to facial skin, lips and eyelashes.

6. The cosmetic composition of my invention is not suggested in the prior art documents.

Indeed, US 6 471 983 discloses a skin application agent containing a polyisoprene latex. In particular, in all the Examples of US 6 471 983, Kraton IR 401 is employed as polyisoprene latex.

The absence of a polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a

molecular weight within the above range, makes the product of US 6 471 983 unsuitable for the preparation of the cosmetic composition of the present invention which is stable, has high film-forming property and is endowed with a homogenous aspect.

At this purpose, I gave proof of the unsuitability of US 6 471 983 product with the experimental data of the analogous comparison product REM 513.34.

Moreover, in US 6 471 983 no specific mention of disteardimonium hectorite has been made among the thickeners.

As far as US 2003/0044469 is concerned, it relates to skin care compositions containing microcapsules prepared by the process comprising: (a) providing an o/w emulsion prepared by combining an aqueous preparation of component selected from the group consisting of retinol and retinoic acid with an oil component in the presence of an emulsifier; (b) combining the emulsion and an aqueous solution of an anionic polymer to form a matrix; (c) contacting the matrix with an aqueous chitosan solution such that membrane-encapsulated products are formed in an aqueous phase; and (d) separating the products from the aqueous phase.

On the contrary the cosmetic composition of the present invention is an anhydrous composition.

Furthermore, no polyisoprene has been mentioned in the skin care composition of US 2003/0044469 and no hint to select the specific disteardimonium hectorite has been made by US 2003/0044469.

Indeed, in the skin care composition of US 2003/0044469 disteardimonium hectorite is embedded in a long list of other thickeners and only in form of a mixture with cyclopentasiloxane and propylene carbonate, i.e. the product Bentone® Gel VS-5PC (Rheox) (US 2003/0044469, [0058]).

In fact, it has to be noted in the o/w emulsion system hydrophilic thickeners such as, for example, xanthan gum and polyacrylates are suitable to be employed.

On the other hand, hydrophobic thickener such as disteardimonium hectorite alone can be used in the o/w emulsion system of US 2003/0044469 only in the form of a mixture with cyclopentasiloxane and propylene carbonate and in the presence of an emulsifier such as cetearyl glucosides (and) ceteryl alcohol, i.e. Emulgade® PL 68/50 product, otherwise the disteardimonium hectorite alone is not capable to be dissolved in such o/w emulsion (see US 2003/0044469, Tables 1 and 2, Encl. A1).

Therefore, the disteardimonium hectorite used in the cosmetic composition of the present invention is not a functionally equivalent thickener to other thickeners such as xanthan gum and polyacrylates since the disteardimonium hectorite is distinguished from such species essentially for its hydrophobic nature and thus its affinity to anhydrous system.

As a further proof that a specific selection of the disteardimonium hectorite has been made, is that not all the Bentones products are suitable to be used in an anhydrous cosmetic composition.

Indeed, for example, Bentone EW (i.e. hectorite) is a rheological additive for aqueous phase of cosmetics and therefore unsuitable to be employed in the present anhydrous composition (see Enclosed A2).

Moreover, I gave proof that the absence of the specific disteardimonium hectorite of the invention leads to an unstable, inhomogeneous and thus not applicable product (see REM 513.33).

It is therefore clear that neither US 6 471 983 nor US 2003/0044469 suggest to select the three specific components: 1) polyisoprene obtainable by the process comprising the steps of a) comminuting a solid polyisoprene with a molecular weight of between 100,000 and 4,000,000 and b) depolymerising the comminuted solid polyisoprene of step a) to a molecular weight within the above range, 2) disteardimonium hectorite and 3) isododecane, as essential elements in order to achieve a stable anhydrous cosmetic composition having high film-forming property and which provides



for the deposition of a homogeneous long lasting film on the facial skin, lips and eyelashes.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and/or imprisonment under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

*March 2, 2009*  
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(date)

*[Signature]*  
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(signature)